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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Lester D. Michels

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Merchant & Gould P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903

EXAMINER

WITCZAK, CATHERINE

ART UNIT

PAPER NUMBER

3767

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/791,370	Applicant(s) MICHELS ET AL.	
	Examiner CATHERINE N. WITCZAK	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21,25-30,32-34 and 36-41 is/are pending in the application.
- 4a) Of the above claim(s) 21,25-30,32-34 and 36-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I in the reply filed on 5/11/10 is acknowledged. Examiner notes that claims 17-20 were inadvertently not included with the claims of group I (as claims 16-20 depend from independent claim 1) in the restriction requirement mailed 4/13/10, but will be examined along with claims 1-16.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites 'wherein each of the first and second catheters have constant wall thickness in the overlap area'. The specification as originally filed does not provide support for this newly added limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. Claims 1 and 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters (US 6,508,807).

Peters discloses a device comprising a first catheter (5) having one end (10) received within the end (21) of a second catheter (2) in an overlap area; a collar (15) with a first opening (42) for encircling the first catheter which is smaller than a second opening (44) for encircling a second catheter, the collar surrounding a portion of the overlap; a clamp (30) encircling a recessed area on the collar and the overlap area; the clamp having a pair of spaced jaws (31/32) and a tongue (48) having teeth to interlock with teeth (49) on the first jaw (31); the diameter of a distal cavity of the collar (from 42) being smaller than the diameter of proximal cavity of the collar (44); wherein the first and second catheter have a constant wall thickness in the overlap area.

Peters discloses the claimed invention except for expressly disclosing the first and second catheters being flexible. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to include flexible catheters in the device of Peters because Applicant has not disclosed that flexible catheters provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would recognize that it is obvious to modify the flexibility of tubing within a medical device system based on desired functioning, and that the connector device of Peters would serve in connecting catheters of varying flexibilities. Therefore, it would have been an obvious matter of design choice to modify Peters to obtain the invention as specified in claim 1.

3. Claims 1 and 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin (US 4,895,570) as modified by Peters.

Larkin discloses a device comprising a first catheter (18) having one end (20) received within the end of a second catheter (12) in an overlap area; a collar (28) with a first opening for encircling the first

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catheter which is smaller than a second opening for encircling a second catheter (Figure 2), the collar surrounding a portion of the overlap; the diameter of a distal cavity of the collar being smaller than the diameter of proximal cavity of the collar (Figure 2); and a collet (22) having a ring portion (48) from which panels (26) extend; and wherein the catheters have a constant wall thickness in the overlapped area.

Larkin discloses the claimed invention except for expressly disclosing the first and second catheters being flexible. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to include flexible catheters in the device of Larkin because Applicant has not disclosed that flexible catheters provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would recognize that it is obvious to modify the flexibility of tubing within a medical device system based on desired functioning, and that the connector device of Larkin would serve in connecting catheters of varying flexibilities. Therefore, it would have been an obvious matter of design choice to modify Larkin to obtain the invention as specified in claim 1.

Larkin discloses the claimed device except for a clamp encircling the collar and overlap area; the clamp having a pair of spaced jaws and a tongue having teeth to interlock with teeth on the first jaw. Peters discloses in Figure 4 that it is known to use a clamp with jaws and teeth. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Larkin with a clamp as taught by Peters since such a modification would provide additional security and protection against infection when connecting two medical tubes to each other.

4. Claims 2 and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin as modified by Peters in further view of Glantz (US 5,558,641).

Larkin as modified by Peters discloses the claimed device except for the device being used to establish fluid communication in a system comprising a reservoir having a pierceable septum and outlet

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tube configured to be received within one end of the second catheter in fluid communication with the reservoir. Glantz et al disclose in Figure 5 that it is known to use catheter connector devices in implantable pump systems. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Larkin as modified by Peters with the teachings of Glantz et al since it is routine practice in the medical art to employ catheter connectors in implantable pump systems such as the one disclosed by Glantz, with the incorporation of the features of the device of Larkin as modified by Peters providing for an implantable pump system with a secure system for preventing the disconnection of the catheter components and thus minimizing risk to patients.

Larkin as modified by Peters disclose the claimed device except for the connector also comprising a sleeve having a flared lip extending from the first portion to surround a portion of the first catheter; the sleeve portion being about 2-6 inches long and having an outer diameter at least about 50% larger than the first catheter outer diameter. Glantz et al disclose in Figures 13 that it is known to use catheter connector devices in which a portion of a first catheter is surrounded by a sleeve having a lip which extends from the connector structure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Larkin as modified by Peters with the teachings of Glantz et al since the incorporation of a sleeve would add support to the first catheter, thus reducing the risk of kinking of the catheter or disconnection from the connector. Although Glantz et al do not expressly disclose the length or diameter of the sleeve portion, it is routine practice in the medical art to vary the sizes of device components depending on the particular use of the device, and thus it would have been obvious to one having ordinary skill in the art to modify the dimensions of the sleeve to match those claimed in claims 12-14 and 17-19.

Response to Arguments

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Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Catherine N Witzak/

Examiner, Art Unit 3767

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767